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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,152	03/16/2001	Christian Behl	MPG-10	2299

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,152

Applicant(s)

BEHL ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 16-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's election without traverse of the invention of Group II, claims 12 and 15-17 in Paper No. 8, received January 31, 2002 is acknowledged.

The cancellation of claims 1-11, 14, and 15 filed in January 31, 2002 is acknowledged. The addition of claims 18-28 filed in January 31, 2002 is acknowledged.

Claims 12 and 16-28 are pending.

The election of species is directed to the invention of Group I, claims 1-11, and 14, drawn to method of treatment. Since applicant elected the invention of Group II herein, the applicant would not be required to make an election of species to claims that drawn to composition herein.

Warning

Applicant is advised that should claim 24 be found allowable, claims 25-28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Please note that the intended use does not lend patentable weight to claims that drawn to compositions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17, 19, 20, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "N-acetyl-tryptophanoctyl-ester", "N-acetyl-tryptophandodecyl-ester", "N-acetyl-tryptophanstearyl-ester", "N-acetyl-tryptophanpalmityl-ester", and "N-acetyl-tryptophanoleyl-ester" in lines 4 – 6; also "N-acetyl-tryptophanethyl-ester". There is insufficient antecedent basis for this limitation in the claim.

Claims 17 and 20 recite the limitation "N-acetyl derivative" in line 1 respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "N-acetyl-tryptophanoctyl-ester", "N-acetyl-tryptophandodecyl-ester", "N-acetyl-tryptophanstearyl-ester", and "N-acetyl-tryptophanpalmityl-ester" in lines 4 – 6; also "N-acetyl-tryptophanethyl-ester". There is insufficient antecedent basis for this limitation in the claim.

Claim 20 recites the limitation "N-acetyl-tryptophanethyl-ester". There is insufficient antecedent basis for this limitation in the claim.

The term "immunosuppressiva" in claim 23 renders the claim indefinite because the term is not understood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kathawala et al. (US Patent 4,448,785 from the IDS received March 16, 2001).

Kathawala et al. teaches N-acyl tryptophan compounds including N-oleoyl-tryptophanethyl-ester (when R¹ is ethyl, R² and R³ are hydrogen, A is oleyl), useful as anti-cholesteric agents (Col. 2, line 65 – col. 3, line 49). Kathawala et al. also teaches that the N-acyl tryptophan compounds may be formulated into solid or liquid pharmaceutical composition (See col. 9, line 29-64).

Kathawala et al. does not expressly teach to employ N-oleoyl-tryptophanethyl-ester specifically into a pharmaceutical composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ N-oleoyl-tryptophanethyl-ester specifically into a pharmaceutical composition.

One of ordinary skill in the art would have been motivated to employ N-oleoyl-tryptophanethyl-ester specifically into a pharmaceutical composition because any

compounds of Kathawala et al., including N-oleoyl-tryptophanethyl-ester, are known to be useful in formulating a pharmaceutical composition. Employing N-oleoyl-tryptophanethyl-ester would have been reasonably expected to be useful for formulating a pharmaceutical composition.

Claims 18-19 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamiya et al. (Hakko Kogaku Zasshi, 1976; 54(6):369-373 from the IDS received March 16, 2001) in view of Stites et al. (Basic & Clinical Immunology, 5th ed. 184, p.34, 36-37).

Nakamiya et al. teaches lauryl esters of different amino acids including tryptophan having anti-bacterial activities (See page 371, Table 1).

Nakamiya et al. does not expressly teach that lauryl ester of tryptophan is useful, alone or in combination with another active, for formulating a pharmaceutical composition. Nakamiya et al. does not expressly teach that stearyl or palmityl esters of tryptophan are also useful for the same purpose.

Stites et al. teaches that immunoglobulin M has a high antibacterial activity (See particular page 34, Table 4-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lauryl ester of tryptophan, alone or in combination with immunoglobulin M, for formulating a pharmaceutical composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ

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the stearyl or palmityl esters of tryptophan, alone or in combination with immunoglobulin M, for formulating a pharmaceutical composition.

One of ordinary skill in the art would have been motivated to employ lauryl ester of tryptophan, alone or in combination with immunoglobulin M, for formulating a pharmaceutical composition because combining two agents which are known to be useful to have antibacterial activities individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

One of ordinary skill in the art would have been motivated to employ the stearyl or palmityl esters of tryptophan, alone or in combination with immunoglobulin M, for formulating a pharmaceutical composition because lauryl ester and palmityl or stearyl ester are similar esters. The only difference between lauryl ester and palmityl or stearyl ester is the carbon chain length, as lauryl has 10 carbon and palmityl has 15 carbon in the carbon chain. Since they have a very similar structure, one of ordinary skill in the art would reasonably expect those esters have similar properties. See *In re Hoch* 166 USPQ 406. Therefore, incorporating the esters compounds herein would have been reasonably expected to be useful in formulating an anti-bacterial composition.

Allowable Subject Matter

Claim 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
May 6, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200